K132189

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Sophono

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510(k) Summary: Otomag Bone Conduction Hearing System

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, this summary of substantial equivalence information is being submitted.

Submitted By: Sophono, Inc.
5744 Central Avenue #100
Boulder, Colorado 80301

Establishment Registration Number: 3008514292

Contact Person:

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Date Prepared: July 12, 2013

Trade or Proprietary Name: Otomag Bone Conduction Hearing System

Regulation Number: 21 CFR §874.3300

Regulation Name: Hearing Aid, Bone Conduction

Regulatory Class: Class II

Product Code: LXB

Panel: Ear Nose and Throat Specialty Panel

Predicate Device: Otomag Bone Conduction Hearing System – K102199

Device Description:

The subject of this Traditional 510(k) is to obtain clearance for a modification in the method of sterilization and packaging for the Alpha (M) Magnetic Implant, cleared under 510(k) K102199, and the Surgical and Implant Templates, via a Letter to File under 510(k) K102199, and to supply these components of the system as sterile. The predicate device components are provided non-sterile and must be sterilized prior to implantation by gravity steam (autoclaving). The proposed method of sterilization for these components is by Ethylene Oxide (EO).

The Otomag™ Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Otomag™ System is configured in either of two configurations. The first configuration is the Alpha (S), where the Otomag™ Sound Processor is attached magnetically to a Headband or Softband. The second configuration is the Alpha (M), where the Otomag™ Sound Processor is attached magnetically to an implanted magnet. The Headband, Softband, or Magnetic Implant holds the sound processor against the head, and vibration is transduced through direct contact with the patient's skin and the bone below.

The Otomag™ System is designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Otomag™ System for individual patient hearing loss.

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Intended Use:

The Otomag Alpha Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Magnetic Implant (patients 5 years of age and up). This is the same intended use, and for the same patient population as the current legally marketed device.

Technological Characteristics:

Technological characteristics of the modified device that are equivalent to those of the predicate device are:

- Overall device performance and operating principle
- Fundamental technology of the device

Technological characteristics that are different between the modified device and the predicate are:

- Packaging and expiration dating: The Magnetic Implant, Surgical Template and Implant Template are supplied on a high-density polyethylene (HDPE) card in double Tyvek pouches.
- Method of Sterilization: The method is by Ethylene Oxide (EO)
- Patient Contact Materials: The Surgical Template is now composed of high-density polyethylene (HDPE) plastic instead of anodized aluminum.

Performance Standards:

The changes reported in this submission for the Alpha (M) Magnetic Implant and accessories conform to applicable requirements of the following National and International Standards.

ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices

ISO 15223-1 Second Edition 2012-07-01, Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements

DIN EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices

EN 556-1:2006 Sterilisation of Medical Devices - Requirements for medical devices to be designated "STERILE" Part 1: Requirements for medical devices that have been sterilised in their final packaging

DIN EN ISO 11138-1:2008 Sterilisation of Health Care Products- Biological Indicators- Part 1: General

EN 1422:2009 Ethylene Oxide Sterilisers- Requirements and Test Procedures

AAMI ANSI ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

DIN EN ISO 10993-7:2009 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide-Sterilisation Residuals

AAMI ANSI ST72:2011 Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

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DIN 58948-7:2010 Sterilisation- Low Temperature Sterilisers - Part 7: Installation Requirements and Service Supply Requirements for Ethylene Oxide Sterilisers

ISO 11607-1: 2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

DIN EN 868-5:2009 - Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods

ISTA 2A 2011 Preshipment Test Procedures

ASTM F1980-07 (Reapproved 2011), Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

ASTM F1929-98 (Reapproved 2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials

Non-Clinical Performance Testing:

Testing included the following:

- Packaging Process Validation: to assure that the sealing of the Tyvek pouches maintains package integrity
- Shipping Validation: to assure product and package meet requirements after exposure to environmental conditions
- Sterilization Validation: to assure a sterility assurance level (SAL) of 10^{-6} using one half cycle
- Sterilant Residuals: to assure that the residuals that remain on the device are considered acceptable per *ISO 10993-7:2009. Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide-Sterilization Residuals.*
- Packaging Validation: to assure seal integrity of the pouches that they would withstand the rigors of the intended sterilization and distribution environments
- Shelf Life Validation: to validate that product and packaging meet requirements after defined shelf life

The modified device has been subjected to extensive safety and verification/validation testing. The testing information presented in this submission demonstrates the device is as safe and effective and substantially equivalent to the predicate device.

Conclusion:

The EO sterilization method, change in patient contact materials, and modified packaging and labeling does not alter the intended use, indications for use or fundamental scientific technological characteristics of the device and all processes have been validated. The materials that compose the Magnetic Implant, Implant Template and Surgical Template meet the requirements of ISO 10993-1 for biocompatibility. Based on non-clinical testing, the changes have been appropriately validated and raise no new questions of safety and effectiveness. The Otomag Bone Conduction Hearing System performs the same and is as safe and effective and considered to be substantially equivalent to the previously 510(k) cleared predicate device (K102199).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Sophono, Inc.
c/o Krista Traynor, M.A., RAC
Director of Regulatory Affairs
5744 Central Avenue #100
Boulder, CO 80301

Re: K132189
Trade/Device Name: Otomag Bone Conduction Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: August 26, 2013
Received: August 27, 2013

Dear Ms. Traynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132189

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag™ Alpha Sound Processor is intended for use with the Otomag™ Headband or Otomag™ Softband (no age limitations), or with the Otomag™ Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10dB on average measured at 0.5, 1, 2, and 4 kHz. or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Cherish R. Giusto -S